IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant(s):	Ballevre et al.
Appl. No.:	09/508,635
Conf. No.:	7617
Filed:	May 18, 2000
Title:	ORGAN SPECIFIC NUTRITION
Art Unit:	1654
Examiner:	D. Lukton
Docket No.:	112701-066

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' REPLY BRIEF

Sir:

I. INTRODUCTION

Appellants submit Appellants' Reply Brief in response to the Examiner's Answer dated May 8, 2006 pursuant to 37 C.F.R. § 41.41(a). Appellants respectfully submit the Examiner's Answer has failed to remedy the deficiencies with respect to the Final Office Action dated November 15, 2005 as noted in Appellants' Appeal Brief filed on March 3, 2006 for at least the reasons set forth below. Accordingly, Appellants respectfully request that the rejections of pending Claims 30, 32, 35 and 37-41 be reversed.

II. CLAIMS 30, 32, 35 AND 37-41 SATISFY THE REQUIREMENTS UNDER 35 U.S.C. §112

a. The phrase "internally administering" is supported by the specification

The Examiner alleges that the several examples set forth in Appellants' specification do not provide a general support for the phrase "internally administering" in Claim 30. See, Examiner's Answer, page 18. The Examiner reasons that, because a couple of additional methods of internally administering (i.e. intravenous administration, intraperitoneal administration and subcutaneous administration) are not specifically disclosed in the specification, there is insufficient support for the phrase "internally administering." Appellants submit that there is explicit support in the specification for oral nutritional forms that can be swallowed and enteral administration of the nutritional formula via nasogastric tubes or enteral tubes, which are all aspects of internal administration. By disclosing oral administration and enteral administration, Appellants have disclosed a number of examples of internally administering forms to distinguish from topically administering forms.

Moreover, the additional commonly known methods of internally administering such as parental administration cited by the Examiner are well within the fundamental knowledge and ascertainable scope of one having ordinary skill in the art (i.e. Ph.D. in clinical nutrition) viewing Appellants' specification. The skilled artisan would understand that Appellants had possession of the present claims in view of Appellants' specification, which would include internally administering the claimed composition. As a result, the phrase "internally administering" is supported by the specification and satisfies the written description requirement.

b. The term "internal" was previously deleted to render its rejection under 35 U.S.C. §112 moot

The Examiner states that there is no descriptive support for the term "internal" in Claim 30 and asserts that Appellants have declined to argue that such support exists. See, Examiner's Answer, page 18, lines 18-20. However, to render moot the new matter rejection under 35 U.S.C. §112, first paragraph, with respect to the term "internal," Appellants agreed to delete this term from Claim 30 and previously submitted an amendment after final to return Claim 30, in

part, to its original form which did not utilize the term "internal" to reduce the number of arguments during the Appeal. The Examiner refused to enter the amendment.

As stated previously, Appellants respectfully submit that they agree to delete this term "internal" in order to render this rejection moot. Thus, Appellants do not understand the issue. The Examiner objects to the term "internal" because of the lack of written description, Appellants have agreed to delete it, but the Examiner refuses to enter the amendment. Appellants respectfully request that this Board enter the amendment.

c. Claims 30, 32, 35 and 37-41 35 are enabled under 35 U.S.C. §112, first paragraph

Regarding the Examiner's enablement rejection, the Examiner asserts that there is no evidence to support the correlation between the rate of protein synthesis and promoting specific organ recovery. See, Examiner's Answer, page 19, lines 7-9. Appellants respectfully submit that the organ recovery can be quantified or defined by measuring beneficial aspects regarding the organ such as, for example, protein concentration, RNA concentration, protein synthesis capacity, protein synthesis rate, daily protein synthesis and ribosomal efficiency as taught by the specification (see Example 2, the tables of pages 21-24). Appellants respectfully submit that they are entitled to define organ recovery in any suitable manner. In turn, the specification teaches various forms of a dietary milk protein hydrolysate that can be selected, for example, to increase protein concentration or rate of protein synthesis in a specific organ (i.e. promote organ recovery). For instance, Examples 1 and 2 show actual experimentation regarding internally administrating the hydrolyzed proteins in mammals and the corresponding increase in protein concentration and rate protein synthesis in particular organs of the mammals.

The Examiner agrees that Appellants have shown that milk protein hydrolysates can increase the rate of protein synthesis in rats. See, Examiner's Answer, page 19, lines 18-19. However, the Examiner states that there is no evidence that the skilled physiologist can "predict" success in the treatment of Crohn's disease, sepsis or diarrhea by administering a compound that increases protein synthesis. See, Examiner's Answer, page 20. In response, Appellants submit that the present claims do not specifically recite treatment of Crohn's disease, sepsis or diarrhea. Instead, the present claims recite, in part, a method of organ recovery as measured by the rate of protein synthesis (e.g. hydrolysis) using milk protein hydrolyzates, which the Examiner admits is

enabled. See, Examiner's Answer, page 19, lines 18-19. Nevertheless, treatment of Crohn's disease, sepsis or diarrhea is a beneficial effect of using the milk protein hydrolysates in accordance with the present invention.

d. Claims 30, 32, 35 and 37-41 35 are definite under 35 U.S.C. §112, second paragraph

As discussed previously, Appellants respectfully submit that the present claims are directed, in part, to a method of promoting specific organ recovery. The organ recovery can be quantified or defined by measuring beneficial aspects regarding the organ such as, for example, protein concentration, RNA concentration, protein synthesis capacity, protein synthesis rate, daily protein synthesis and ribosomal efficiency as taught by the specification (see Example 2, the tables of pages 21-24). The treatment of Crohn's disease, sepsis or diarrhea is a beneficial effect of the claimed methods directed to internally administering the milk protein hydrolysates. The benefits of treating hepatitis, cirrhosis and kidney infection by internally administering the milk protein hydrolysates in accordance with the present invention have not been determined at this time. As a result, the skilled artisan would understand the metes and bounds of the present claims in view of Appellants' specification, which would include internally administering the claimed composition and promoting specific organ recovery.

Accordingly, Appellants respectfully submit that the rejections of Claims 30, 32, 35 and 37-41 under 35 U.S.C. §112, first and second paragraphs, are improper and should be reversed.

III. A PRIMA FACIE CASE OF OBVIOUSNESS HAS NOT BEEN ESTABLISHED

Appellants respectfully request that the Board reverse the section 103 rejections because the Examiner has still failed to show that the cited references, alone or in combination, disclose or suggest every element of the present claims.

In the Examiner's Answer, the Examiner withdraws the rejections under *Nakamura* and *Masuda*. See, Examiner's Answer, page 3. The Examiner maintains the rejections of *Nakamura* in view of *Ichikawa* or *Masuda* in view of *Ichikawa*. The Examiner states that *Ichikawa* discloses that ACE inhibitors in general exhibit a therapeutic effect on kidneys. See, Examiner's

Answer, page 21, lines 12-14. Nevertheless, *Ichikawa* still fails to remedy the deficiencies of *Nakamura* and *Masuda*. For example, like *Nakamura* and *Masuda, Ichikawa* fails to disclose or suggest a method for selecting a form of a dietary milk protein hydrolysate (e.g. based on degree of hydrolysis) which increases protein concentration or rate of protein synthesis in a specific organ as required, in part, by the present claims. The Examiner has failed to provide any support within *Ichickawa* regarding same. As a result, *Nakamura* in view of *Ichikawa* or *Masuda* in view of *Ichikawa* fail to disclose or suggest every element of the present claims.

The Examiner states that *Gordon* teaches that milk protein hydrolyzates can be used to treat vascular tumors or arthritis as evidence of internal administration. See, Examiner's Answer, page 22, lines 8-10. However, Appellants respectfully submit that vascular tumors (near the surface of the skin) and arthritis can be treated with topically administered products (e.g. ointments). From all of his examples and explicit teachings, *Gordon* is entirely directed to applying an enzyme modified casein topically to the surface of the skin or hair. As a result, *Gordon* fails to provide any motivation or suggestion for internally administering and fails to disclose or suggest the present claims. See, *Gordon,* column 3, lines 4-10.

The Examiner states that *Verma* is used to teach that skin is an organ. See, Examiner's Answer, page 23, lines 1-4. Nevertheless, using *Verma* in this manner still fails to remedy the deficiencies of *Gordon* as discussed previously. In other words, *Gordon* in combination with *Verna* fails to disclose or suggest internally administering a milk protein hydrolysate as required, in part, by the present claims.

Like *Nakamura* in view of *Ichikawa* or *Masuda* in view of *Ichikawa*, the Examiner misunderstands Appellants' arguments regarding *Smith*, *Qu*, *Stalker*, *Gray*, *Van Leeuen*, *Panigrahi* and *Boza*. With respect to these remaining rejections, the Examiner states that selecting a particular degree of hydrolysis, which is admittedly not taught by *Smith*, *Qu*, *Stalker*, *Gray*, *Van Leeuen*, *Panigrahi* and *Boza*, is not required by the claims. However, as discussed previously, Appellants respectfully submit that the present claims recite, in part, selecting a form of a dietary milk protein hydrolysate, which increases protein concentration or rate of protein synthesis in the specific organ. The specification teaches that selecting a form of a dietary milk protein hydrolysate involves selecting the milk protein hydrolysate based on degree of hydrolysis. See, specification, page 2, line 35 to page 4, line 9; page 5, lines 1-30. By internally administering the selected protein source of a specific degree of hydrolysis, a specific organ will

benefit most. In view of this, the skilled artisan would understand that the claimed invention requires selecting a form of a dietary milk protein hydrolysate based on its degree of hydrolysis in accordance with the specification. Moreover, because *Smith*, *Qu*, *Stalker*, *Gray*, *Van Leeuen*, *Panigrahi* and *Boza* fail to disclose or suggest at least these elements, they fail to disclose or suggest every element of the present claims.

Appellants respectfully submit that, as clearly demonstrated herein, the cited references, alone or in combination, fail to disclose or suggest every element of the claimed invention. Accordingly, Appellants respectfully submit that the obviousness rejections of Claims 30, 32, 35 and 37-41 are improper and should be reversed.

IV. CONCLUSION

For the foregoing reasons, Appellants respectfully submit that the Examiner's Answer does not remedy the deficiencies noted in Appellants' Appeal Brief with respect to the Final Office Action. Therefore, Appellants respectfully request that the Board of Appeals reverse the 35 U.S.C. §112, first and second paragraphs, and 35 U.S.C. §103 rejections with respect to Claims 30, 32, 35 and 37-41.

No fee is due in connection with this Reply Brief. The Director is authorized to charge any fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-66 on the account statement.

Respectfully submitted,

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